

## **REMARKS**

### **Priority**

The Examiner stated that no claim of priority under 35 USC § 120 has been made on the Oath/Declaration. The Applicant respectfully submits that it is not necessary to make a claim of priority in the Oath/Declaration under 35 USC § 120. As stated in the MPEP at 201.11(C) the later filed application must contain a specific reference to the prior application in the specification or in an application data sheet. A reference to the prior application to which the current application claims priority was made in an amendment to the specification submitted on March 16, 2004.

### **Drawings**

The Examiner objected to the drawings as failing to comply with 37 CFR 1.84(p)(5) because the reference numbers in the specification do not match the reference numbers in the drawing, e.g. in Fig. 3A the lumen is referred to as 300 in the drawing, but referred to as 301 in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are being submitted with this response to change the reference numeral of the lumen from 300 to 301 in Fig. 3A.

### **Claim Rejections - 35 U.S.C. § 112**

The Examiner has rejected claims 2 and 3 under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner has rejected claims 2, 3, 8, and 19-22, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant

believes that this rejection is improper as the claims in question were present upon the initial filing of the application. It is improper to reject, under the written description requirement, such claims. Applicant has, however, amended the claims, without admitting that this rejection is proper, in order to further prosecution of the application. The amended claims satisfy section 112.

**Claim Rejections - 35 U.S.C. § 102**

The Examiner has rejected claims 1, 2, 5, 6, 7 and 8 under 35 U.S.C. 102(b) as being anticipated by Etzion et al. (J Mol Cell Cardiol, 2001) in light of Lewin (Genes VII, 2000). The Examiner has rejected claims 1, 5, 6 and 7 under 35 U.S.C. 102(b) as being anticipated by Leor et al. (Cardiovascular Research, 1997). The Examiner has rejected claims 1, 5, 6 and 7 under 35 U.S.C. 102(b) as being anticipated by Pouzet et al. (Circulation, 2001). The Examiner has rejected claims 1, 5, and 6 under 35 U.S.C. 102(b) as being anticipated by Soykan et al. (US Patent No. 6,151,525). The Applicant respectfully traverses. The cited references fail to anticipate all elements of the Applicants' claims. In particular, the cited references fail to teach the element of independent claim 1 of "*delivering a non-antigenic cell line comprising  $\alpha$ -1,3-galactosyltransferase (GGTA1) knock-out swine cells to the infarct region within the ventricle of the human subject.*" In contrast, Etzion teaches the transplantation of embryonic cardiomyocytes into the left ventricle of rats after extensive myocardial infarction of the rats myocardium. Leor teaches the transplantation of fetal cardiomyocytes or skeletal muscle cells into a myocardial infarction. Pouzet teaches delivering skeletal muscle cells to an infarct region. Soykan teaches delivering undifferentiated contractile cells to an infarct region. Lewin fails to teach the delivery of cells to an infarct region at all. Therefore, the Applicant respectfully submits that the cited references fail to anticipate independent claim 1 and the claims that depend upon and incorporate the limitations of claim 1.

**Claim Rejections - 35 U.S.C. § 103**

The Examiner has rejected claims 2-4 under 35 USC 103(a) as unpatentable over Etzion et al. (J Mol Cell Cardiol, 2001) in combination with Gustafsson et al. (U.S. Patent No. 6,153,428). The Applicant respectfully traverses. Claim 2 has been cancelled, claim 3 has been amended, and claim 4 has been incorporated into claim 1. The Applicant respectfully submits that the claims as amended are not obvious in light of Etzion in view of Gustafsson. In particular, the Applicant submits that there would be no motivation or suggestion to one of ordinary skill in the art to combine Gustafsson with Etzion to teach the element of claim 1 (previously the element of claim 4) of “*delivering a non-antigenic cell line comprising  $\alpha$ -1,3-galactosyltransferase (GGTA1) knock-out swine cells to the infarct region*”.

Etzion teaches transplanting isolated, purified, and cultured rat cardiomyocytes into the infarcted regions of rat hearts seven days after myocardial infarction. Etzion also teaches that using immunosuppression or inbred animals may avoid possible immune rejection by a rat to transplanted rat cells. Gustafsson teaches the production of swine organs or tissue or cells that do not express  $\alpha$ -1,3-galactosyltransferase. These genetically engineered swine organs or tissue or cells are created to eliminate the production of carbohydrate moieties having distinctive terminal Gal $\alpha$ 1-3Gal $\beta$ 1-4GlcNAc epitope that is a significant factor in xenogeneic, particular human, transplant rejection of swine grafts so that when transplanted into a human there is no hyperacute rejection of the transplanted swine grafts. Hyperacute rejection is a very rapid and severe humoral rejection which leads to the destruction of the swine graft within minutes or hours of the xenographic transplant into a human. The production of carbohydrate moieties having the distinctive terminal Gal $\alpha$ 1-3Gal $\beta$ 1-4GlcNAc epitope is the cause of the hyperacute rejection of swine graft transplants within humans.

Therefore, although Etzion suggests the use of immunosuppression to avoid immune rejection of cells implanted within the same species from which the cells were derived, Etzion fails to suggest immunosuppression as a solution for the specific problem of hyperacute rejection of swine grafts transplanted into humans. One of ordinary skill in the art would not turn to Gustafsson to provide immunosuppression for the transplant of cells

within the same species. The Applicant respectfully submits that the suggestion of immunosuppression of Etzion would not provide motivation to one of ordinary skill in the art to combine Gustafsson with Etzion to solve the specific problem of hyperacute rejection. As such, the Applicant submits that independent claim 1 and all claims that depend upon and incorporate the limitations of claim 1 are not obvious in light of Etzion in view of Gustafsson.

The Examiner has rejected claims 19-22 under 35 USC 103(a) as unpatentable over Soykan et al. (US Patent No. 6,151,525) in combination with Chachques. (U.S. 2002/0124855A1) and further in combination with Gustafsson et al. (US Patent 6,153,428). The Applicant respectfully traverses. The cited references, either individually or in combination, fail to teach or render obvious all of the elements of the Applicants' claimed invention. In particular the cited references fail to teach the element of claim 19 of "*applying a pacing therapy to the ventricle to pre-excite the infarct region to unload the infarct region from mechanical stress; and delivering an at least one structurally reinforcing component to the infarct region after applying the pacing therapy.*" In contrast, Soykan teaches applying electrical stimulation after new contractile tissue has been formed by the previous implantation of undifferentiated contractile cells. In Col. 13 lines 10 – 15 Soykan discloses "[t]he present invention also includes an electrical stimulation device 22. This provides the necessary electrical pulses at the correct time to make the newly formed contractile tissue beat in synchrony with the rest of the heart muscle." Similarly, Chachques teaches implanting myogenic cells into a damaged myocardium and "[f]ollowing implantation, electrical stimulation is applied to facilitate synchronization of the transplanted cells" (Pg. 2 paragraph 28.) Gustafsson fails to teach the application of a pacing therapy to a heart. Therefore, the Applicant respectfully submits that the independent claim 19 as amended and the claims that depend upon and incorporate the limitations of claim 19 are not taught or rendered obvious by the cited references.

**Double Patenting**

Claims 1, 5, and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 4 of copending Application No. 10/414,602. Claims 1 and 5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 3 of copending Application No. 10/414,767. The Applicants' respectfully submit that the claims as amended render the double patenting rejection moot.

**PETITION FOR EXTENSION OF TIME PURSUANT TO 37 C.F.R. § 1.136 (a)**

Applicant respectfully petitions pursuant to 37 CFR 1.136(a) for a two month extension of time to file this response to the Office Action mailed May 17, 2005. The extended period is set to expire on October 17, 2005. A check in the amount of \$450.00 is enclosed to cover the fee for a two month extension of time.

If there are any additional charges, please charge Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN

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